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3PP

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BACKGROUND

PFOS (perfluorooctane sulfonic acid) is a member of a large family of sulfonated perfluoro-chemicals (total annual production of the PFOS family is < 10 million lbs) which are used for a wide variety of industrial, commercial, and consumer applications (including use as a component of soil and stain-resistant coatings for fabrics, leather, furniture, and carpets, in fire-fighting foams, commercial and consumer floor polishes, cleaning products, and as a surfactant in other specialty applications). Pesticidal and indirect food use products are also made from this technology.

All of these chemicals have the potential to degrade back to PFOS which does not appear to degrade further (it is thus highly persistent). 3M Corporation is the sole US manufacturer of the PFOS family of chemicals.

PFOS has been found widely in human blood samples (ppm levels in manufacturing workers, ppb levels in non-exposed workers and in blood bank samples) based on 3M research. PFOS has also been found in wildlife species across the US (especially in fish eating birds) and was detected in naive (unexposed) laboratory rats (the PFOS contamination was traced back to fish meal used in the rat chow).

PFOS caused postnatal deaths (and other developmental effects) in offspring in a 2-generation reproductive effects rat study (NOAEL of 0.1 mg/kg/day and LOAEL of 0.4 mg/kg/day). At higher doses in this study, progeny in the first generation died, while at the LOAEL reduced pup weight gain was observed.

PFOS accumulates to a high degree in humans and animals. It has an estimated half-life of 4 years in humans. It thus appears to combine Persistence, Bioaccumulation, and Toxicity properties to a high degree.

3M had previously launched a major research effort on PFOS to characterize its environmental presence, environmental and human effects, and environmental fate. EPA continues to receive the results of this work and will make it available as it comes in.

EPA REVIEW

Preliminary data indicated to EPA that PFOS is of significant concern on the basis of evidence of widespread human exposure and indications of toxicity in the 2-generation rat study. In addition, EPA's preliminary risk assessment indicated potentially unacceptable margins of exposure (MOEs) for workers and possibly the general population.

There are many assumptions and considerable uncertainty in these arguments and analyses. It is not possible at present to judge the adequacy or accuracy of the MOE analyses or whether the exposure levels used in the above estimations may be considered representative of the affected populations at large.

EPA has requested detailed information from 3M and a large body of information has been received but not fully reviewed. Review of subchronic studies provided by 3M on monkeys and rats also show deaths at doses similar to those reported in the 2-generation study.

3M has raised questions regarding the possible relevance to humans of a proposed mechanism (effects on cholesterol biosynthesis) for PFOS's lethal effect in the 2-generation study. The proposed mechanism, the company argues, affects reproductive outcomes in litter bearing animals due to its inhibitory effect on a burst of cholesterol biosynthesis in the critical period just before birth.

The proposed mechanism would, if demonstrated, have broad implications for and present significant potential concerns for humans and environmental organisms. At this time it is not clear what is going on in PFOS toxicology – nonetheless, the persistent presence of deaths in multiple studies involving multiple species at roughly equivalent doses raises flags.

PHASE OUT DECISION BY 3M

Following a series of discussions with EPA, and based on concerns about the widespread presence and longer term risks presented by PFOS, 3M announced that it would exit worldwide from this market by about the end of the year, although it may need to extend the time period for some critical uses (e.g., fire fighting foam).

EPA agrees that continued manufacture and use of PFOS represents an unacceptable technology that should be eliminated to protect human health and the environment from potentially severe long term consequences. The company has committed to continue its research effort despite the commercial decision. 3M has expressed interest in collaborative efforts with EPA as they withdraw from the market and in the development of safer substitutes.

EPA is currently examining appropriate regulatory alternatives necessary to protect human health and environment in light of 3M's phaseout decision on PFOS. More information will be made available as our strategy becomes clarified.

EPA strongly supports continued research on PFOS to improve our understanding of it fate and effects to humans and the environment. A more complete understanding of the environmental fate of PFOS derivatives, including polymers, is particularly important to allow an assessment of the longer term consequences of the PFOS which has been released into the environment.

EPA is prepared to work with industry, both manufacturers and users, to assist in review of critical uses of PFOS to ensure that good decisions are made in those cases where risk/risk

tradeoff issues are presented by the phaseout decision. These uses include fire fighting foam and acid mist suppression.

PFOS ALTERNATIVES AND RELATED SUBSTANCES

Users of PFOS-based products are confronting the need to replace PFOS. Various materials have been identified as substitutes for these uses. EPA recommends that alternatives be carefully evaluated to identify possible hazard or risk issues. EPA is prepared to work with individual manufacturers of alternatives which are available or under development as substitutes for PFOS to ensure that good decisions are made.

As the work on PFOS progresses, EPA plans to broaden its review to encompass other highly fluorinated acids, including PFOA and other materials, including the telomers.

PFOA

PFOA (perfluorooctanoic acid) is closely related structurally to PFOS and is used as a solvent for certain polymerization reactions. EPA has requested information from producers and will be preparing an assessment. Based on preliminary information, PFOA presents a different hazard, exposure, and risk picture compared to PFOS. 3M has also committed to ending production of PFOA. There are other producers in the US and EPA is examining its options regarding action on PFOA. We are aware of industry concerns regarding the availability of substitutes for PFOA in its fluoropolymer reaction solvent application.

TELOMERS AND OTHER PERFLUORO CHEMISTRIES

EPA has not yet looked into the telomers and other perfluoro chemistries. The ITC will be requesting information on a broad array of fluorinated derivatives and we will be working with them as part of our assessment effort. The telomers represent an interesting alternative to PFOS and we encourage industry efforts to inform EPA and others regarding the fate and effects of these materials. Of particular interest to EPA in this regard is to understand the environmental fate of these materials, including to what extent do the various derivatives degrade to PFOA and what are the rates and extent of this degradation under various environmental conditions.